IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC AND EDWARDS LIFESCIENCES PVT, INC.,	)	
Plaintiffs	)	
v.	)	C.A. No. 12-023-GMS
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,	)	
Defendants.	)	

MEDTRONIC'S OPENING BRIEF IN SUPPORT OF ITS RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FED. R. CIV. P. 50(b)

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I. INTRODUCTION

Given the massive verdict in this case, and the many important legal issues it raises, the Court's consideration of this motion for judgment as a matter of law is an especially important safeguard. As will be seen, the verdict is legally unsupported and should be reversed.

For starters, the jury did not follow the Court's instructions, rendering the verdict unsupported. Regarding lost profits, for example, the Court instructed the jury that "Edwards may not be compensated for lost profits of any of their affiliates or subsidiaries." But the $393 million verdict is based on the profits of all Edwards' affiliates and subsidiaries in defiance of that instruction. *See* Tr. 818:8-9 (Edwards's damages expert: "So the [$]393 [million] is certainly based on the profits of the entity as a whole."). Put starkly, the jury awarded over $100 million in lost profits that this Court instructed it not to award. Not only does this necessitate setting aside the verdict, it is a red flag warranting heightened scrutiny of the verdict overall.

Even more fundamentally, the liability finding is premised on a gross misapplication of the patent that this Court has itself described as apparently "erroneous and misguided." D.I. 139 at 2 n.2 ("[A] reading of claim 1 that would require only the frame, and not the other crucial components of the prosthetic valve, to be compressed and introduced into the patient's vasculature appears erroneous and misguided."). This Court's instinct is on target. The claims require that the patented frame **with** the prosthetic valve must fit in a 5.7 mm introducer. As this Court explained, Edwards' naked-frame infringement theory is inconsistent with the purpose of the patent, which is to introduce into the body a frame **with** the prosthetic valve. *Id*. Both during claim construction and pretrial, the Court recognized that the applicant "told the PTO that Dr. Cribier's invention was different than the prior art because there was 'no teaching or suggestion in the cited references' regarding a prosthetic valve assembly that included a stent, a valvular structure[,] and an internal cover, where the entire assembly was collapsible to a diameter of '5.7

mm or less . . . .'" D.I. 103 at 3-4 n.4. It is beyond legitimate dispute that CoreValve's assembly is larger than 5.7 mm, negating the possibility of infringement.

Because there is no infringement of the claims when properly applied, liability thus depends on what this Court subsequently called a "sanction" in which it precluded Medtronic from arguing that the claims require the entire CoreValve assembly to fit in the 5.7 mm introducer. A fresh look with a complete record establishes that this sanction is not well-founded and, in all events, by allowing a massive verdict based on an erroneous and misguided reading of a patent, it is far too drastic for the perceived transgression. The Court concluded that Medtronic should have raised the issue of Edwards' naked-frame infringement theory earlier in the case. But this Court's *Markman* Order made clear that the complete assembly must fit in the 5.7 mm introducer. There was thus no reason for Medtronic to re-raise that issue. And Medtronic had argued exactly this during the claim construction proceedings so the issue was in fact raised to the Court during *Markman*, except that Edwards did not contest this point. Indeed, it was Edwards that had raised the naked-frame infringement theory belatedly—even though this Court had explained in its *Markman* Order that the applicant had distinguished the prior art by contending that the "entire assembly" must be collapsible to a diameter of 5.7 mm or less. Under the stringent *Pennypack* standard, this sanction is not justified and should be vacated. Once that is done, JMOL should be entered for Medtronic under the proper application of the claims.

And there are other legal flaws in the verdict. The § 271(f) infringement finding for foreign sales is unwarranted. Among other problems with foreign sales liability is that the pericardial sacs supplied from the United States are commodity raw materials that are not themselves combined with the frames and are not especially adapted for infringement. The evidence is unanimous on both these points and thus JMOL is appropriate because key legal

requirements are unsatisfied. On invalidity, the patent does not enable the claimed invention and, because it is so thin on teaching, if the claims are deemed enabled, they must be held obvious.

Finally, there is no substantial evidence to support the willful infringement finding. There is no basis at all to conclude that a reasonable person would have had to be reckless to believe that CoreValve was not infringing or that the claims were invalid. Medtronic's legal positions were not reckless and this objective prong is to be reviewed by the Court *de novo*. There also is no substantial evidence to establish the subjective prong of the willful infringement test. There is no evidence, much less clear and convincing evidence, that Medtronic infringed with intent to violate Edwards' patent rights.

II. NON-INFRINGEMENT

A. The Jury's Finding that the CoreValve Directly Infringes the Asserted Claims Fails as a Matter Of Law.

Each asserted claim requires that the prosthetic valve frame be compressed so that it can be introduced into a patient's vasculature using a catheterization technique through "a sheath with a diameter of 5.7 mm or less that facilitates delivery of a catheter to an artery." D.I. 103 at 3. This claim requirement is not met and JMOL is warranted for two independent reasons.

First, the patent as properly understood requires that the frame **with** the prosthetic valve must fit through the 5.7 mm diameter introducer, not merely a naked frame that has no purpose. This Court has acknowledged that the naked-frame construction applied at trial "appears **erroneous and misguided**." D.I. 139 at 2 n.2. [1] The Court should not sustain a massive verdict based on what it has recognized as an erroneous construction of the claims.

[1] Emphasis supplied unless otherwise specified.

The verdict is the product of what the Court subsequently characterized as a "sanction" against Medtronic for supposedly failing to raise the naked-frame issue with the Court sooner. The record, and governing legal standard, do not support this decision. The Court should correct this by rejecting the verdict which is founded upon a legally erroneous application of the patent.

Second, there is no substantial evidence to support the verdict even under the erroneous jury instruction the Court gave regarding this claim limitation.

1. Judgment as a matter of law should be entered because Edwards relied upon an infringement theory that this Court recognized as apparently "erroneous and misguided."

In addressing JMOL, the Court must apply the correct construction of the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975-76 (Fed. Cir. 1995) (affirming JMOL based on post-trial claim construction not included in the jury charge because it was the correct construction and the proper law must be applied). An implausible application of claim language cannot be tolerated on JMOL. *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1369 (Fed. Cir. 2012) (an infringement claim should be rejected as a matter of law if it is not consistent with the "the plain and ordinary meaning of the [claim] term").

a. Edwards' naked-frame infringement theory is legally "erroneous and misguided."

In its December 18, 2013 ruling, the Court acknowledged that Edwards' naked-frame infringement theory apparently applies a misguided and legally erroneous reading of the patent. Specifically, the Court correctly observed that "a reading of claim 1 that would require only the frame, and not the other crucial components of the prosthetic valve, to be compressed and introduced into the patient's vasculature appears **erroneous and misguided**." D.I. 139 at 2 n.2.

To support this strong statement, the Court acknowledged that "the **invention is a prosthetic valve** that can be implanted by a catheterized technique" and that "the frame

implanted without the flexible valvular structure and the internal cover is **incapable of achieving the goals of the invention**." *Id.* The Court explained that "the frame and the flexible valvular structure and the internal cover taken together form the prosthetic valve that is to be compressed and implanted according to the terms of claim 1." *Id.*

The Court's instinct about the proper way to apply the asserted claims set forth in the December 18 Order matches the reasoning in its *Markman* Order. That Order made plain that the asserted claims necessarily require the **entire prosthetic valve** to pass through a 5.7 mm or less introducer. D.I. 103 at 3-4 n.4. In discussing the key intrinsic evidence, the Court repeatedly referred to the collapsibility of the entire device, quoting the patent's teaching that "the **prosthetic valve** should have the 'smallest possible external diameter'" and it "would be 'acceptable' if **it** could be introduced into the femoral artery through 'even a 18F (5.7mm) introducer.'" *Id.* The "it" obviously refers to the frame **with** the valve—not a naked frame.

The Court's analysis of the file history in the *Markman* Order mandates the same conclusion. It establishes that, as a matter of law, the object that must fit through the 5.7 mm introducer is the frame **with** the prosthetic valve. Specifically, the Court explained that the inventors distinguished the prior art by representing to "the PTO that Dr. Cribier's invention was different than the prior art because there was 'no teaching or suggestion in the cited references' regarding a **prosthetic valve assembly** that included a stent, a valvular structure[,] and an internal cover, where **the entire assembly was collapsible to a diameter of '5.7 mm or less** for advancement through an introducer and into a patient's vasculature via a catheterization technique.'" D.I. 103 at 3-4 n.4. The Court thus recognized the patentee's very direct distinction of the prior art based, not on a naked frame, but on its assertion that according to the invention, the "**entire assembly** was collapsible to a diameter of '5.7 mm or less.'" Finally, the Court

rejected Edwards' attempt to add the word "about" to the construction, concluding that "in consideration of the patentee's representation to the PTO that the **claimed invention** is collapsible to a diameter of 5.7 mm or less, the court concludes that 'about' should not be included in this term's construction." D.I. 103 at 4 n.4.

The intrinsic evidence from the patent confirms that the Court had it right in its *Markman* Order and December 18 Order. The patent consistently refers to the diameter of the introducer in terms of the **entire prosthetic valve assembly**, not a naked frame, which would be useless. The Abstract states that the frame is compressible "for delivery" through a 5.7 arterial introducer:

> The frame is compressible **for delivery** into a patient's vasculature **through an 18 F (5.7 mm)** arterial introducer using a catheterization technique.

It would defy common sense to compress something **for delivery** through an introducer if there would be no reason to deliver such an object into the body. The Abstract is unquestionably stating that it is the frame with the prosthetic valve that must fit through a 5.7 mm introducer.

The specification reinforces this conclusion. It states that when "folded by compression, the diameter of said frame is about 4 to 5 millimeters, in view of its transcutaneous introduction in the femoral artery through an arterial sheath of 14 to 16 F . . . i.e., about 4.5 to 5.1 mm." PTX 2 at 8:62-66. The specification explains that the valvular structure must be fastened on the inside surface of the frame, and that "[a]fterwards, it is compressed in its minimal size, i.e., 4 or 5 mm, in diameter in view of its introduction in the femoral artery." *Id.* at 9:49-55. The "it" being referred to in this passage of the patent is the "IV," which is an acronym defined in the patent as "implantable valve." *Id*. at 1:35-37. The patent further states that the "valvular structure 14 is compressed inside the frame 10 when this is in its compressed position (FIG. 4*a*), i.e., it fits into a 4 to 5 mm diameter space." *Id.* at 10:24-26. The patent leaves no doubt that it is the frame **with**

the valve that must be compressed to fit within the introducer for introduction into the body.

The key section that addresses the importance of a narrow valve is also unambiguous that the reference to the 5.7 mm introducer applies to the frame **with** the prosthetic valve:

> Since it is aimed at being positioned in the heart after having been introduced by a catheterization technique by a transcutaneous route in a peripheral artery, mainly the femoral artery, **the IV [implantable valve] should preferably have the smallest possible external diameter.** Ideally, it should be able to be introduced in the femoral artery through a 14 F (4.5 mm) size arterial introducer which is the size of the arterial introducer commonly used to perform an aortic dilatation. However, a 16 F (5.1 mm) or even a 18 F (5.7 mm) introducer would also be acceptable.

Id. at 14:4-13.

b. The sanction should not be permitted to allow a massive judgment based on a legally erroneous reading of the claims.

Because the claims properly applied cannot cover the CoreValve, the massive verdict was made possible only by what the Court subsequently called a "sanction."[2] That devastating sanction should be set aside. As Edwards' counsel stated when addressing this dispute at the pretrial conference, "there is no doubt under the law Your Honor retains discretion to address these issues at any time as long as this Court has jurisdiction over the case." D.I. 131 at 76:7-11.

With a complete record, it is clear that permitting a legally erroneous infringement verdict is manifestly unjust and based on errors of law and fact. The "exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Leeseberg v. Converted Organics Inc*., No. 08-926-GMS, 2011 U.S. Dist. LEXIS 21183, at *16, (D. Del. Mar.

[2] In its December 18, 2013 Order, the Court did not expressly exclude evidence or refer to any "sanction." On the first day of trial the Court excluded evidence that the entire CoreValve device—including the tissue valve and skirt—does not fit through an 5.7 mm or less introducer. The Court did not refer to its exclusion of evidence as a "sanction" until the charge conference.

3, 2011) (Sleet, CJ) (quoting *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel Co*., 777 F.2d 113 (3d Cir. 1985), *aff'd*, 482 U.S. 656 (1987)). "Courts within the Third Circuit evaluate harmlessness and substantial justification based on the following factors: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence." *Id.* at *15-16.

None of these factors support the December 18 ruling. There was no surprise, prejudice or bad faith as explained below. The Court's ruling started from the erroneous premise that it was Medtronic's burden, not Edwards', to raise this issue earlier. From the outset, Edwards' infringement contentions specified that it is the entire CoreValve device that is compressed such that it fits through a 5.7 mm introducer. In its claim chart opposite the "18 French" limitation, Edwards identified the CoreValve product with the valve as allegedly meeting this limitation: "The CoreValve 2009 Product Brochure depicts the Generation 3 PAV [prosthetic aortic valve] in both compressed and expanded form, and identifies that the **device** is deliverable via an 18 French arterial introducer." D.I. 133, Ex. 3 at 5. Nothing in Edwards' contentions points to a naked frame, stripped of the valve. Medtronic, therefore, had no reason to believe that the claims needed to be construed to foreclose an infringement theory that was not advanced by Edwards.

During *Markman* briefing, **both sides** were explicit that the "18 French" limitation applied to the entire device. Edwards certainly did not propose its "naked-frame" claim construction. To the contrary, Edwards unequivocally stated that "'an 18 French arterial introducer' is sized to permit **delivery of a device**." D.I. 53 at p. 12; *see also id.* ("an 18 French

arterial introducer may be slightly larger than 18 French to permit **delivery of an 18 French device**."). Edwards' assertions now that it always argued that it was just the "frame" are unsupported. In fact, as this Court noted in its *Markman* Order, Edwards advanced a construction that the term meant **6.0 mm**—precisely the size of an introducer that is necessary to fit the **entire** CoreValve device.

Medtronic's position—adopted by the Court—was clear. Medtronic's construction was that the 5.7 mm diameter introducer is "for transcutaneous introduction of the **prosthetic valve**." D.I. 56 at 9. Medtronic thus specified in its proposed construction that the 5.7 mm introducer had to accommodate the frame **with** the valve. Medtronic's position was amplified in its brief where it relied on the portion of the prosecution history in which the applicant distinguished the prior art based on its position that the prior art did not disclose that the "entire assembly was collapsible" to a diameter of 5.7 mm. *Id.* at 10. At oral argument, Medtronic repeatedly referred to the entire prosthetic assembly as being collapsible to 5.7 mm or less. D.I. 86 at 68:19-24 (asserting that "none of the prior art showed **a device** that could be compressed to 5.7 millimeters); 70:22-71:2 ("[a]bove this size, the introduction of the **I.V. [implantable valve]** in the femoral artery should probably be done by a surgical technique"); 72:3-11 ("wherein **the entire prosthetic valve assembly** is collapsible to a diameter of 5.7 millimeters"); 73:5-75:13 (distinguishing between device dimension and sheath dimension).

It was only days before the *Markman* hearing that Edwards first raised, in Dr. Buller's expert report, an infringement theory that the claim only requires the frame to be compressible to 5.7 mm or less. Edwards made no mention of this position during the *Markman* hearing.[3] But

[3] The naked-frame theory is directly contrary to Edwards' admissions before the EPO on nearly identical claim language. There Edwards admitted that "**the frame is compressible to an external diameter does not mean anything else than that in fact the entire prosthetic valve**

Footnote continued on next page . . .

Edwards' report did nothing to reasonably place Medtronic on notice that it needed to take action to counter Edwards' naked-frame position beyond the claim construction positions documented above. Rather, if Edwards wanted to pursue a counter-intuitive application of the claims in the face of the Court's *Markman* Order, the burden should have been on Edwards to join this issue. Indeed, Dr. Buller's report appeared to **support** the proper reading of the patent in important ways. His report explained that a key benefit of the claimed invention is that it minimizes the compressed diameter of the **prosthetic valve**, not a naked frame:

> the '825 Patent teaches design features of transcatheter prosthetic valves that **minimize the compressed diameter of the prosthetic valve** for delivery into a patient via a catheterization technique.

Ex. A at 35. Dr. Buller then quoted the passage in the patent that states the "IV should preferably have the smallest possible external diameter." *Id.*

The Court's December 18, 2013 Order faults Medtronic for not raising Edwards' naked-frame position after the issuance of the Court's *Markman* Order. However, as explained above, that Order is best read to have embraced the natural reading of the patent: it is the frame **with the prosthetic valve** that must fit in the 5.7 mm introducer. Medtronic's May 3, 2013 summary judgment letter was clear that Medtronic viewed Edwards' naked-frame infringement theory as a "non-sensical reading of the plain language of the claim, specification, and prosecution history." D.I. 107 at 2. Medtronic also pointed out that the *Markman* Order supported its position by

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assembly is compressible to said diameter." D.I. 135, Ex. 2 at ¶ 42. In addition, this theory is contrary to Edwards' admissions in a German proceeding involving a foreign counterpart to the '825 patent. There, a three judge panel found Medtronic's device does not infringe the '825 patent's counterpart based on **facts admitted by Edwards**. The panel stated: "The arguments in the briefs of **the parties agree** in the assumption **that a catheter with an external diameter of 6 mm is necessary for the opposed prosthetic valve assembly**." D.I. 145, Ex. 1 at 15. The panel found "[a]n external diameter of 5.95 mm – in the case of a claimed external diameter of not more than 5.7 mm – lies outside the scope of protection of the patent." *Id.* The Court excluded evidence from these proceedings.

relying upon the prosecution history that the "**entire** prosthetic valve assembly" must be collapsible to a diameter of 5.7 mm. *Id.* Medtronic did not obscure its position in any way.

Medtronic thus had no reason to petition the Court to consider Edwards' naked-frame argument as a viable new claim construction issue after the *Markman* Order. If anyone, it was Edwards that should have raised the issue. Nonetheless, the Court denied Medtronic's motion *in limine*, and permitted Edwards to advance its theories at trial. In denying Medtronic's motion, the Court did not adopt any additional construction of the "frame" or "18 French" limitations. During trial, Medtronic was not permitted to challenge Edwards' infringement theories based on the undisputed fact that Medtronic's device, as actually made and sold, cannot be delivered through a 5.7 mm introducer because that device in fact contains tissue inside the frame—the very tissue that is necessary for the CoreValve device to function as a prosthetic valve.

Deciding this case based on the conclusion that it was Medtronic, not Edwards, that should have raised this issue after the claim construction briefing is inconsistent with the governing Third Circuit *Pennypack* standard on sanctions. *See Pennypack*, 559 F.2d 894 at 905 ("the exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence."). Medtronic did not violate any rule, much less did it commit a flagrant violation. Nor was there prejudice to Edwards that could support such a severe sanction. The *Pennypack* factors simply do not support this sanction in any way.

After the close of evidence, the Court instructed the jury, based on an unjustified sanction, on a construction that this Court has recognized as apparently "erroneous and misguided." Because Medtronic does not infringe as a matter of law under a legally proper understanding of the patent, the massive verdict is unwarranted.

2. No reasonable jury could find that the CoreValve frame is "compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique."

There is no evidence that the CoreValve frame is capable of being introduced into a patient's vasculature using a catheterization technique through "a sheath with a diameter of 5.7 mm or less that facilitates delivery of a catheter to an artery." D.I. 103 at 3. The sole evidence of infringement relating to this claim term was Dr. Buller's testimony and the testimony of Russell Hodge, the Senior Program Manager for the CoreValve device. The testimony of each of these witnesses confirms that the CoreValve cannot meet this limitation.

The CoreValve frame only fits through an introducer sheath that is **6.0 mm** in diameter using Medtronic's catheterization technique. Mr. Hodge testified that to implant the CoreValve device, physicians must first cool the device, which allows the Nitinol frame to be compressed around the leaflets and skirt. The device is then loaded into a capsule to keep the valve in its compressed state. Tr. 883:8-888:8. After the CoreValve is placed within a capsule, it is introduced by catheter into a patient's vasculature through an introducer sheath that is 6.0 mm in diameter. This is because the outer diameter of the capsule—which is necessary to keep the frame compressed—is 6.0 mm in diameter. Tr. 888:16-17, 945:17-23. As Mr. Hodge testified:

Q. Could you deliver the CoreValve product via a catheterization technique without the sheath – I mean without the capsule?

A. Absolutely not.

Q. Why not?

A. Because it would immediately expand out of your hands as you were trying to load it into the introducer sheath.

* * *

Q. You wouldn't be able to introduce it via a catheterization technique?

A. Correct.

Tr. 962:19-963:8. Only once the CoreValve has been positioned within the native aortic valve, via catheter, can the capsule be removed. Tr. 860:11-863:8; 880:23-889:24; 935:18-937:2; 943:10-947:3; 962:19-963:8. Medtronic does not make, use, sell, offer for sale, or import an accused product that is introduced into a patient's vasculature using Medtronic's catheterization technique without this capsule. Tr. 962:19-963:8.

Dr. Buller agreed. He admitted that the CoreValve device must be "squeezed down, compressed and held in by something" in order to be delivered into a patient's vasculature. Tr. 731:16-19. He further admitted that the capsule is necessary to deliver the CoreValve:

> To deliver this device – and this is the device when it already has the valve and the covering inside it – **it is compressed onto a delivery system and retained inside a sheath**. It is compressed by cooling it down in water. It makes the metal more easy to compress. It is slid inside the sheath which is put over it. And then that sheath is moved into the body with the device, the whole device, including the valve inside it. Tracked up into the patient's heart, into their diseased chalky aortic valve. **And then it is released by slowly withdrawing the sheath so that the device expands**.

Tr. 729:1-16.

Because the frame must be "squeezed down, compressed and held in by something," infringement cannot be shown based on the diameter of the compressed valve without the capsule. Dr. Buller admitted that the CoreValve frame is compressed to 5.5 mm. Tr. 556:12-23. He also admitted that the CoreValve device is in fact compressed with "the sheath they choose to use," which is, by Dr. Buller's admission, approximately .25 millimeter thick. Tr. 556:10-11. Since .25 mm is added on each side of the compressed frame, the CoreValve frame requires an introducer with a diameter of 6.0 mm or larger in order to be introduced into a patient's vasculature using a catheterization technique. Medtronic spent "many millions of dollars of effort" to introduce the prosthetic valve frame using a catheterization technique that was less than 6.0 mm, but they "failed ten out of 16 requirements related to inability to completely get the

implant into that delivery system." Tr. 889:14-20; *see also* 963:13-15. Because the CoreValve undisputedly cannot be delivered using a catheterization technique through a sheath that is less than 6.0 mm, no reasonable jury could find that the CoreValve could fit through a sheath that is 5.7 mm or less.

Edwards sought to present evidence that a naked CoreValve frame is compressible to 5.7 mm or less—a theory that this Court stated was "erroneous and misguided." There is no evidence that a naked frame compressed to this size is capable of being introduced into a patient's vasculature using Medtronic's catheterization technique, as required by the claim. Mr. Hodge testified that "the frame by itself doesn't get delivered into a patient." Tr. 951:15-18. He further explained that "a frame wouldn't have any purpose of being delivered in a patient by itself." Tr. 953:2-3; *see also* 937:1-2, 946:5-12. Dr. Cribier testified that a patient would die if only a "stent" without the other elements of the invention were implanted. Tr. 286:22-287:12.

Edwards presented no evidence that Medtronic makes, uses, sells, offers for sale, or imports an accused product that is simply a naked frame without any tissue for introduction into a patient's vasculature using a catheterization technique. The prosthetic valve frame of Medtronic's accused CoreValve device is not capable of introduction into a patient's vasculature through a 5.7 mm or less arterial introducer using a catheterization technique.

3. No reasonable jury could find that the CoreValve frame "resists recoil."

There is no evidence that the CoreValve frame "resist[s] the recoil force exerted by the stenosed aortic valve" because there is no recoil force generated during implantation of the CoreValve device, a self-expanding valve. Dr. Buller admitted that recoil is a phenomenon associated with balloon expansion, not a self-expanding valve. Tr. 678:22-680:2; 685:3-686:21.

Dr. Cribier explained that recoil is caused when the annulus is expanded. Tr. 289:3-8. He further testified that the annular recoil is caused by the deflation of a balloon that expands the

annulus in order to implant a balloon expandable stent:

> Q. And that's because when that balloon is taken away, this tissue, this annular tissue, it recoils, it comes back in?
>
> A. Yes.
>
> Q. Right. That is the recoil that you wanted to make sure you designed the stent was strong enough to withstand. Right?
>
> A. Exactly.

Tr. 298:8-15. When the balloon is deflated, the stenosed tissue "recoils" back, pushing against the prosthetic valve with a force that the frame must be strong enough to resist. Tr. 300:1-11. Dr. Cribier repeatedly testified that it is important to design the frame with the strength to maintain circularity. *See* Tr. 300:17-18; 306:5-6, 306:14-23. Dr. Cribier explained that the circularity is necessitated by the fact that the leaflets of the claimed prosthetic valve are at the same level as the native valve, and therefore, the frame needs to be circular to allow the leaflets to lie flat, or coapt. Tr. 301:19-302:14; *see also* Tr. 303:3-11. The frame, therefore, must not be flexible in order to resist this recoil. Tr. 307:8-19; Tr. 308:6-8. Accordingly, Dr. Cribier testified that he understood that a self-expanding frame **could not** resist recoil. Tr. 310:6-311:25.

Mr. Hodge testified that Medtronic's self-expanding device does not generate recoil. Rather, the flexible Nitinol frame conforms to the shape of the native aortic annulus. He also testified, the CoreValve frame "grows in to essentially conform to fill the space that the anatomy allows it to fill, again, without creating this excessive force and creating the phenomenon that we call recoil." Tr. 860:7-10. *See also* Tr. 858:11-12; Tr. 878:8-19; Tr. 971:4-22; PTX 333-1 at 66. Specifically, Mr. Hodge testified that if the native anatomy is irregularly shaped or has calcium deposits, the resulting shape of the implanted valve will be irregular. "It's not going to force the anatomy to be in a different shape." Tr. 866:22-867:1. Mr. Hodge explained:

> Q: We've heard a lot in this case about recoil, Mr. Hodge, and I would like to unpack it a little bit. What's being referenced there?
>
> A: Sure. Again, I will go back to the examples that were talked about earlier. When you blow something up with a balloon and you have a balloon-expandable stent, you have to overextend that, especially if you are trying to create a round structure what you want to stay in place, because when you take the balloon out, the force of the anatomy is going to require recoil force and it's going to want to come down. So you need to make that strong. **With a self-extending implant**, the body offers a certain structure there that's not filled. So when we put this implant in, it's made out of shaped memory metal, it grows, but **it grows to fill the space that the body allows it to grow**. It does not force itself beyond and to try to make that structure round because it's a round structure when it's in air. But when you see images of the implant in the body, it's never round. **It's always irregularly configured because the body is allowed to impart a neutral part of situation or an equilibrium situation where the implant just resides in the space**.

Tr. 868:24-869:21; *see also* DX235-0005; Tr. 876:13-877:6. In fact, as Mr. Hodge testified, **Medtronic informed the FDA (before the asserted claims were even filed) that the CoreValve was different from a balloon-expandable frame and that it does not have recoil**. Tr. 970:1-971:22; PTX 333-1 at p. 66.

Dr. Loomis similarly testified regarding the properties of the CoreValve Nitinol frame, and explained that there is no "recoil force" to "resist," as the asserted claims require. Tr. 1116:14-1121:22; 1122:25-1123:5; 1129:18-21; 1130:19-1132:8. As Dr. Loomis explained, a balloon-expandable stent "stiffens" so the "stent actually resists the force," whereas the Nitinol frame "complies with the force." Tr. 1151:14-17. "[C]ompliant and resistant are total, total opposites, a hundred degrees apart." Tr. 1151:19-21; *see also* Tr. 1151:22-1153:6.

Edwards knows that the self-expanding CoreValve frame does not resist recoil, so it attempted to meet its burden by pointing to the use of a balloon pre- and post-dilatation in Medtronic's catheterization technique. But no reasonable jury could find infringement based on this evidence. As Mr. Hodge testified, the annulus is "never overexpanded"—not during pre-

dilatation, implantation, or post-dilatation. Tr. 964:14-17; *see also* Tr. 965:22-966:1; Tr. 966:2-968:10; DTX 164-0056. Mr. Hodge explained that the balloons are "undersized" meaning "[t]hey are smaller than the labeled frame size." Tr. 968:11-16; *see also* Tr. 859:17-19. Indeed, despite Edwards' assertion, Dr. Buller **admitted** that pre-dilatation balloon valvuloplasty does not infringe claim 1 of the '825 patent. Tr. 689:11-690:1.

Edwards also fails to meet its burden by pointing to evidence that the CoreValve frame has high radial strength. As Mr. Hodge testified, "[i]t doesn't mean it's got so much radial strength that this part of the valve can't conform to an annulus that looks irregular." Tr. at 969:3-25. And, while the lower portion of the CoreValve frame does have a higher radial strength, the claim requires the frame to "resist the recoil force exerted by the stenosed aortic valve." At trial, Edwards focused solely on the portion of the asserted claims "for providing the frame with sufficient radial strength," and **ignored** the claim requirement that the frame also "resist the recoil force exerted by the stenosed aortic valve." Tr. 563:16-565:22. Dr. Buller did not testify or opine that recoil is generated during the implantation of Medtronic's self-expanding CoreValve device. Tr. 563:16-567:12. Edwards, therefore, failed to meet its burden to show that that there is **any** recoil force exerted by the stenosed aortic valve during the implantation of the CoreValve. The proper remedy is judgment as a matter of law of non-infringement.

B. The Jury's Finding of Infringement Under 35 U.S.C. § 271(f) Lacks Support.

Even if there were infringement for the CoreValve assembled in the United States, no reasonable jury could find infringement for the CoreValve products assembled in Mexico based on Medtronic's shipment of fixed pericardial sacs from the United States.

1. No reasonable jury could find that the pericardial sac constitutes multiple "components" or that the pericardial sac is "combined" under Section 271(f)(1).

No reasonable jury could find that the shipment from the U.S. of pericardial sacs meets

the requirements of 35 U.S.C. § 271(f)(1). The jury was instructed that Edwards needed to prove that Medtronic supplied "components" from the United States and that Medtronic intended that the components be "combined outside the United States." Edwards failed on both points.[4]

The plain language of § 271(f)(1) requires that multiple "components" be supplied from the United States for liability. The phrase "such components" appears **twice** and dictates a construction of the statute that precludes infringement based on the exportation of a single component. The phrase is first used to refer to what is supplied from the United States because that portion of the statute describes the state of the components while in the United States.

The plural "components" throughout § 271(f)(1) stands in distinct contrast to § 271(f)(2), which consistently uses the singular "component." Had Congress intended subsection (f)(1) to apply to the exportation of a single component, as it clearly intended for subsection (f)(2), it could have readily used the same language. *See Russello v. United States,* 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

The Supreme Court has stated that § 271(f)(1) requires more than one component to be supplied from the United States: "the two paragraphs differ, among other things, on the quantity of components that must be 'supplie[d]. . . from the United States' for liability to attach."

[4] The pericardial sacs are not "components" under 35 U.S.C. § 271(f). To be components, they must be actually incorporated into the allegedly infringing device. *See Microsoft Corp. v. AT&T Corp*., 550 U.S. 437, 453, 458 (2007) ("Section 271(f) does not identify as an infringing act conduct in the United States that facilitates making a component of a patented invention outside the United States . . . ."). Here, the exported sacs are commodity raw material from which the components are made. As raw material, the sacs themselves are not combinable until after extra steps are taken outside of the United States—*e.g.*, the laser-cutting of the sacs into leaflets and skirts that are actually incorporated into the accused CoreValve devices.

Microsoft, 550 U.S. at 454 n.16; *see also id.* at 458 n.18 (contrasting § 271(f)(1)'s coverage, which applies to all or a substantial portion of a patented invention's components with § 271(f)(2)'s coverage, which "applies to the export of even a single component" under certain circumstances).[5]

Limiting § 271(f)(1) to the supply of multiple components is especially appropriate in light of the emphasis that the Supreme court has placed on construing the statute narrowly given its extraterritorial application. *Microsoft,* 550 U.S. at 454; *see also Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.,* 576 F.3d 1348, 1362 (Fed. Cir. 2009) (en banc) ("The [*Microsoft*] Court sent a clear message that the territorial limits of patents should not be lightly breached.").

Section 271(f)(1) unequivocally requires that "all or a substantial portion" of the **components** be supplied from the U.S. But Edwards set forth no evidence that any alleged components for the CoreValve products other than the pericardial sacs are shipped from the United States. Medtronic's export of the pericardial sac, even if it were a component of the claimed invention, is only a single supplied component and thus the jury's verdict cannot stand.

The evidence was undisputed that all other CoreValve components originate elsewhere. Mr. Montecalvo testified that other than the pericardial sacs, Medtronic does not provide any "component" of the CoreValve device from the U.S. A German supplier ships Nitinol frames directly to Medtronic Mexico. Tr. 1011:24-1012:1. Suture is supplied directly from Europe. Tr. 1012:2-4. The leaflets and skirts are cut and processed in Mexico. Tr. 1011:7-15. The other components of Medtronic's catheterization technique, including the compression loading system

[5] Other courts have reached this conclusion. *See, e.g., Ormco Corp. v. Align Technology, Inc.,* 609 F. Supp. 2d 1057, 1074 (C.D. Cal. 2009) (§ 271(f)(1) does not apply when one component is supplied); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.,* No. 95-8833, 2001 U.S. Dist. LEXIS 16895, at *12 (S.D.N.Y. Oct. 19, 2001) (§ 271(f)(1) requires supply of multiple components).

as well as the delivery system are supplied from Ireland. Tr. 1012:10-14. Edwards therefore has not met its burden to show that "all or a substantial portion of the components" are supplied from the United States, and the proper remedy is judgment as a matter of law of non-infringement.

Edwards also failed to meet its burden because the evidence establishes unequivocally that the porcine pericardial sac is not combinable to create the accused product. Tr. 668:19-669:9. The pericardial sac cannot be the basis for infringement under §271(f)(1) which requires that the components be **combined**. Mr. Montecalvo testified that the pericardial sac is not sewn into the frame. Tr. 1011:11-15. Edwards' liability expert, Dr. Buller **admitted** that the fixed porcine pericardial sac is not, and cannot, be sewn to the frame to make the CoreValve products. Tr. 665:11-23. That admission undermines Edwards' entire claim.

Judgment as a matter of law on Edwards' claim under § 271(f)(1) is appropriate.

2. No reasonable jury could have found evidence of active inducement.

Active inducement under § 271(f) requires culpable intent to encourage the violation of that statute. *See Global-Tech Appliances, Inc. v. SEB SA,* 131 S. Ct. 2060, 2070 (2011) ("We think these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence."). Medtronic proposed the following language to be included in the instruction for the elements of liability under § 271(f) (Medtronic's proposed language in italics):

> (2) Medtronic intended that the *exported* components be combined outside the United States *knowing that would cause patent infringement*;

D.I. 163 at Proposed Instruction 3.6.

There is no reason to construe "active inducement" under § 271(f) differently from how it is construed under § 271(b) to require culpable intent to violate the statute. "A standard principle of statutory construction provides that identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Services, Inc.*, 551 U.S.

224, 232 (2007). That principal has special force here, because "the term 'actively induce'" in § 271(f)(1) was expressly "drawn from existing subsection 271(b)." 130 Cong. Rec. H10525, H 10526 (Oct. 1, 1984); *see also Liquid Dynamics Corp. v. Vaughan Co., Inc.,* 449 F.3d 1209, 1222 (Fed. Cir. 2006) (applying § 271(b) standard for active inducement in case brought under § 271(f)(1)). As described in reference to the willful infringement verdict, Edwards presented **no evidence** that Medtronic was reckless, much less that it had an intent to cause a violation of § 271(f). Judgment of a matter as law of non-infringement under § 271(f) is proper.

3. No reasonable jury could find that the pericardial sac is not suitable for substantial non-infringing use or that Medtronic knew that the sac was "especially adapted for use in the invention" under § 271(f)(2).

No reasonable jury could find that shipment from the U.S. of the pericardial sacs meets §271(f)(2)'s requirements for two independent reasons: (1) the exported pericardial sac is a commodity suitable for substantial non-infringing uses, and (2) given the commodity nature of the sacs there is no evidence that Medtronic knew the **sac** was "especially adapted for use in the invention." Edwards bears the burden on both of these issues. *Toshiba Corp. v. Imation Corp*., 681 F.3d 1358, 1362 (Fed. Cir. 2012). Yet Edwards set forth no evidence to meet its burden.

The testimony was undisputed that Medtronic's exported sac is a commodity suitable for non-infringing uses. Mr. Torrianni, testified that "[o]nce it's preserved, once you reach its fixation point, the material is what we tend to term kind of a biomaterial commodity." Tr. 982:20-23; *see also* Tr. 982:25-984:20 (fixed porcine pericardium sacs are commodities available from third party vendors in the same form as used for CoreValve); Tr. 1002:23-1003:5 (regardless of differences in fixation, no difference in material). Dr. Loomis called the material "an **article of commerce**." Tr. 1110:20.

Edwards' counsel acknowledged that "the end result, the desired end result is the same." Tr. 998:12-14. Dr. Buller admitted that fixing tissue in glutaraldehyde is commonly done. Tr.

672:11-13. He further admitted that glutaraldehyde fixed porcine pericardium has substantial uses other than for in the CoreValve. Tr. 670:17-22; 671:2-672:7. Finally, he admitted that he didn't know if it was possible to use Medtronic's fixed porcine pericardium in other applications, and that he would need more information to make that determination. Tr. 672:14-21; 673:10-24.

On this record, no reasonable jury could find infringement under § 271(f)(2), and judgment as a matter of law for Medtronic is proper.

III. INVALIDITY

A. The Jury's Finding that the Asserted Claims Are Valid Lacks Support.

1. No reasonable jury could find that the asserted claims were enabled.

No reasonable jury could conclude that the '825 patent enables one skilled in the art to make the claimed prosthetic valve. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *MagSil Corp. v. Hitachi Global Storage Techs*., 687 F.3d 1377, 1380 (Fed. Cir. 2012) (internal quotation marks omitted).

The claimed prosthetic valve includes a frame that is expandable for implantation in the stenosed aortic valve, has sufficient radial strength to resist the recoil force exerted by the stenosed aortic valve, and is compressible to be introduced through a 5.7 mm or less arterial introducer and into a patient's vasculature using a catheterization technique.

That the claimed stent is capable of delivery through a 5.7 mm diameter introducer is a novel aspect of the claim, and as such this limitation must be enabled by the specification. *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007). The patent explains the implantable valve "should preferably have **the smallest possible** external diameter." PTX 2 at 14:7-8. Edwards acknowledged that making a device "that would be a small enough style to be inserted into a catheter" is one of the patent's goals. Tr. 154:2-4.

Edwards also argued to the PTO that this limitation distinguished the claimed invention from the prior art, asserting that there was "no teaching or suggestion in the cited references" regarding a prosthetic valve assembly that included a stent, a valvular structure and an internal cover, where the entire assembly was collapsible to a diameter of "5.7 mm or less for advancement through an introducer and into a patient's vasculature via a catheterization technique." DTX 322-1068. This Court relied specifically on the patent owner's "5.7 mm or less" distinction over the prior art in construing the claim.

No reasonable jury could conclude that the '825 Patent discloses to one skilled in the art how to actually build **any** prosthetic valve as claimed with a stent that could be introduced through a **5.7 mm** introducer. As Dr. Cribier admitted, the inventors themselves never designed or built a prosthetic valve frame compressible to 18 French, and, not only did they not have a solution to this problem, their patent application did not teach anyone how to do it:

> Q. Now, when you filed the European patent application on December 31 of 1996, you absolutely did not have a solution to the problem of compressing a valve stent to a size that it could be delivered in an 18-French introducer. Correct?
>
> A. Yes.
>
> Q. **And the patent does not tell you how to build a valve stent to a size that can be compressed for delivery through an 18-French introducer. Right**?
>
> A. **Yes**.

Tr. 335:17-25. He further agreed that in 1996 he was "not able . . . to make a stent that was corresponding to the ideas that [he] had in mind for the implantable valve" and "did not possess the knowledge of how to reduce the size of a stent from 22 to 21 French." Tr. 324:24-325:3; 325:17-20. Dr. Cribier's failure was not an inability to "make it with his own hands" or that he was not "a metal fabricator" and cannot "cut metal microscopically to make a stent" as Edwards

argued in closing. Tr. at 1450:2-19. The inventors had not actually solved the problem of a device capable of introduction through an 18 French arterial introducer, and therefore failed to enable one of ordinary skill in the art to make and use the claimed invention.

Dr. Cribier "had absolutely no idea" if the device of his invention would be hard to make. Tr. 325:4-9. Instead, he agreed that he contemplated that a person from Johnson & Johnson would assist "in developing the device so that it would work," but that "project failed completely." Tr. 333:14-334:6; DTX 106-0003. Dr. Cribier further agreed that from July 1996 through 1998, "virtually no work was done on solving the stent problem" and that "it was after the patent application was filed . . . on December 31st of 1996 that [he] began [his] work with the Aran engineers to evaluate what would be a solution to the stent problem." Tr. 339:15-25.

Dr. Cribier sought the expertise of the ARAN engineers to build his valve such that it could be delivered through an 18 French arterial introducer. Dr. Cribier knew a balloon expandable device would have a larger profile than a self-expanding device, which would make it harder to deliver it into a patient's vasculature. Tr. 312:17-313:2. But Dr. Cribier agreed that the problem of finding a material strong enough to resist recoil force and also capable of being crimped down to a small enough size to accomplish the goals of his invention were related. Tr. 312:1-6. Dr. Cribier therefore asked the ARAN engineers, in 1999, to evaluate whether self-expanding Nitinol could be used, but it was determined that the resistance to recoil force was not sufficient in a Nitinol self-expanding stent. Tr. 311:1-25. There is thus no enablement of a Nitinol self-expanding frame that meets the claim limitations. *See e.g.,* Tr. 1180:5-15; Tr. 1181:6-18. Dr. Loomis agreed the claimed invention was not enabled. Tr. 1062:22-1063:3.

In short, there was no legally sufficient evidentiary basis for a reasonable jury to find the asserted claims to be enabled and judgment as a matter of law is appropriate.

2. Judgment as a matter of law should be entered because it is undisputed that the full scope of the asserted claims is not enabled.

Judgment as a matter of law should also be entered in Medtronic's favor because the evidence undisputedly establishes that the full scope of the claim is not enabled. The enablement requirement serves two functions: it prevents inadequate disclosure of the claimed invention, and it prevents claims broader than the disclosed invention. *MagSil*, 687 F.3d 1377 at 1380-81. "Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.* at 1381. "The enablement doctrine's prevention of over broad claims ensures that the patent system preserves necessary incentives for follow-on or improvement inventions." *Id.* at 1384.

In *MagSil*, the Federal Circuit upheld an invalidity finding based on claims with the limitation "a change in resistance of at least 10%." *Id.* at 1381. The specification taught that the inventors' best efforts achieved a maximum change of only 11.8%, but MagSil had failed to disclaim the claim's infinite scope. *Id.* MagSil's expert testified that a person of ordinary skill could achieve change between 100% and 120% without undue experimentation. *Id.* at 1382.

The Federal Circuit found this testimony insufficient: "Even if [the expert's] testimony could somehow overcome the requirement that the enabling disclosure must appear in the specification at the time of filing, his assertions also fail to reach the modern dimensions of this filed of invention. . . . The invention claims resistive changes from at least 10% up to infinity." *Id.* Noting that "MagSil's difficulty in enabling the asserted claims is a problem of its own making," the Federal Court held that "the asserted claims are invalid for lack of enablement because their broad scope is not reasonably supported by the scope of enablement." *Id.* at 1384.

The same analysis applies here. The asserted claims of the '825 patent broadly cover prosthetic valves "capable of being introduced through an 18 French arterial introducer." This

limitation contains no lower bound. It includes, for example, devices capable of being introduced through a 16 French introducer, as set forth in dependent claim 8, and devices capable of being introduced through a 14 French introducer, as set forth in dependent claim 9. It also, necessarily, would include devices capable of being introduced through a 12 or 10 French introducer.

Yet Dr. Cribier freely admitted before the jury that 14 French "was the best that I could hope would be possible to make." Tr. 317:25-318:4. Based on the inventor's own testimony, the claims cover devices that the inventor did not believe were enabled. Dr. Buller agreed:

> Q. Can one of ordinary skill in the art, as of December 31 of 1996, make and use the invention claimed in Claim 1 armed with the patent specification and the knowledge of one skilled in the art with a device that is at 10 French?
>
> A. No, I don't believe they could make one and enable it at 10 French for the whole claim, for everything in the claim.

Tr. 655:4-10. Dr. Buller admitted the claim has no lower limit. Tr. 656:20-21. Edwards never disclaimed the scope below 5.7 mm, and to the contrary affirmatively offered evidence both with respect to its infringement and validity theories that relied on a range of sizes below 5.7 mm, including Medtronic's statements to the FDA that testing had been performed on frames crimped to diameters of 4.75 mm, 5.46 mm, and 5.5 mm.[6] *See* D.I. 167-3 at 10; Tr. 495:11-496:16.

Dr. Buller attempted to save the claims by testifying they were enabled "in the range of 4 or 5 millimeters," but, just as in *MagSil*, Dr. Buller's testimony cannot save the '825 patent, which claims devices capable of introduction through introducers from 18 French down to less than 3 French. *See* Tr. 656:4-9. Accordingly, just as in *MagSil*, the claims are invalid because the full scope has not been enabled. *See* 687 F.3d at 1381-82. Judgment as a matter of law should be

[6] Critically, none of these statements prove that Medtronic's device has been, or is capable of being, introduced through an introducer with a diameter of 5.7 mm or less because they are not measurements of the device as it is delivered using Medtronic's catheterization technique.

entered in Medtronic's favor.

3. No reasonable jury could find that the asserted claims are valid in view of the written description requirement of 35 U.S.C. § 112.

The written description requirement exists to ensure that an inventor sets forth in his specification what he invented, to "'allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010). To satisfy the written description requirement, "the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)).

To the extent the asserted claims cover the self-expanding CoreValve device, the claims are invalid as a matter of law for failure to provide sufficient written description for the limitation "providing the frame with sufficient radial strength **to resist the recoil force** exerted by the stenosed aortic valve." The patent discloses only a balloon-expandable frame. During prosecution, Edwards told the PTO that "[t]he device of the invention is unique in that it must be capable of resisting the powerful recoil force and of withstanding **the forceful balloon inflation** necessary to deploy the implantable valve." DTX 320-0219. The Court nevertheless construed the asserted claims, at Edwards' urging, to encompass frames that are balloon expandable—as well as those that are self-expanding—so long as the valve frame "is capable of increasing or being increased in diameter." D.I. 103 at 4.

Dr. Cribier's testimony explains the patent's lack of disclosure of a self-expanding frame. Dr. Cribier agreed that in 1999, several years after he filed his patent application, he was still trying to find out how we was going to implement his idea for a transcatheter valve. Tr. 309:6-

310:5. At that time, he asked the engineers at ARAN to evaluate a self-expanding valve. The ARAN engineers concluded that a self-expanding Nitinol frame would not have sufficient resistance to the recoil force of the aortic annulus to maintain the circular shape that was essential to the functioning of the prosthetic valve. Tr. 310:6-312:10.

Dr. Cribier also volunteered that previously he "had exactly the same response from ATS Medical when we were discussing the program with them." Tr. 310:13-25. In Dr. Cribier's own words, "two different people said that the self-expanding would not be enough to open circularly the valve for calcification or stenosis," so this result "was most expected." *Id.* Dr. Cribier further testified that he never experimented with self-expanding Nitinol. Tr. 313:18-23. Accordingly, not only did Dr. Cribier consider a self-expanding device to be incapable of meeting the requirements of his invention, every person Dr. Cribier consulted in an effort to solve the problems his invention was intended to overcome reached the exact same conclusion.

Based on the lack of disclosure of any self-expanding embodiment, coupled with Dr. Cribier's unequivocal admission that a self-expanding valve could not satisfy the goals of his invention, there was no legally sufficient evidentiary basis for a reasonable jury to find in favor of Edwards on the written description requirement.

In addition, at Edwards' urging, the Court construed the asserted claims as covering a device in which the frame only, without any tissue inside, is compressed and delivered through an introducer with a diameter of 5.7 mm into a patient's vasculature using a catheterization technique. The claims are therefore invalid for the second, independent reason that they lack written description support for the limitation "the frame being compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique" under such a construction. As Dr.

Loomis testified, in response to questions from Edwards' counsel, the patent fails to describe such a device:

> Q. Now, is there any specific thing in Claim 1 of the '825 patent that you can tell me in your opinion is not described in the patent specification?
>
> A. The patent specification does not, to me, does not describe a frame that has to fit through a 5.7-millimeter introducer. It only describes a complete valve that has to fit through it. Those words in the claim saying that that frame has to fit through the introducer, there is no written description supporting that limitation.

Tr. 1187:22-1188:5. Dr. Cribier agreed that his patent did not describe introduction of the frame only into a patient's vasculature:

> Q. And I'd like to go to your patent, PTX-2. . . . And what it says at Column 3, Lines 40 to 46 is that another aim -- starting right here, Doctor. Another aim of the present invention is to provide an efficient prosthesis valve which can be implanted by a catheterization technique, in particular, in a stenosed aortic orifice . . . . So your goal ultimately was to get an entire valve into the aortic annulus; correct?
>
> A. Yes.
>
> Q. And that would be necessary in order to do anything to help the patient; correct?
>
> A. Yes.

Tr. 286:1-21. As Dr. Cribier testified, if the stent itself, without the other elements of the invention, was put into a human being, that patient would die. Tr. 287:7-12. The patent therefore provides no description of a frame only that is capable of being introduced through an arterial introducer and into a patient's vasculature using a catheterization technique, as required under the construction imposed by the Court. Judgment as a matter of law is the appropriate remedy.

4. No reasonable jury could find that the asserted claims are non-obvious.

A patent is invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. Regardless of what the jury accepted as a person skilled in the art, the asserted claims of the '825 patent are obvious as a matter of law.

Dr. Buller admitted that the Andersen patent discloses or renders obvious all limitations of claims 1 and 2, except for the claimed internal cover. Tr. 617:14-619:16. But Dr. Buller admitted that covers were disclosed in Andersen:

> A. These are two figures from the Andersen patent . . . showing that the concept of mounting a permanent tissue heart valve inside a stent, would also include the cover of the stent. . . . So, again, this is a teaching of a permanently implantable tissue valve, and it can have a covering put on the stent.

Tr. 499:2-17; *see also* Tr. 628:23-629:9; DTX 229 at Fig. 11, Fig. 12, and 4:3-6. Dr. Buller further testified that by the end of 1996, covers on stents were made of various materials, including pericardium. Tr. 499:18-500:3. Dr. Loomis testified that U.S. Patent No. 5,855,601 to Bessler, among other references, also discloses an internal cover. Tr. 1084:1-1085:15; DTX 189 at Fig. 1, Fig. 4, 5:24-27, 5:36-42, 9:26-27.

The record further establishes that one skilled in the art would have understood to modify the cover disclosed in Andersen or to combine Andersen with the internal cover disclosed in Bessler to achieve the internal cover of claims 1 and 2 of the '825 patent. As Dr. Loomis testified, Andersen and Bessler both disclose implantable artificial valves. Tr. 1083:20-1084:3.

Dr. Cribier conceded the point on direct examination:

> Q. How did your invention eliminate the risk of regurgitation?
>
> A. Well, we are were trying to at least decrease the risk of regurgitation by covering the stent. And you are seeing a picture of my drawings initially. **Obviously, we had to cover the stent**, the base of the stent at the level of stent that was implanted to avoid the blood flow directly from the aorta on the site of the valve.

Tr. 263:9-16.

One of ordinary skill in the art would have been motivated to modify the internal cover of Andersen and Bessler based on the very nature of the problem Andersen addressed, prosthetic valves, to achieve the internal cover of claims 1 and 2 in the '825 patent. *KSR Int'l. v. Teleflex*, 550 U.S. 398, 421 (2007) ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.") Dr. Loomis testified that Bailey listed a number of problems in design of any percutaneous valve that had to be considered, and Bailey specifically identified perivalvular leak. Tr. 1051:7-19; PTX 346-0006.

Claims 4 and 5 add limitations that relate to the valvular structure. As Dr. Loomis testified, those limitations are present in any tri-leaflet valve, including the tri-leaflet valves that were in the prior art. Tr. 1088:4-1091:23. Dr. Loomis's testimony that prior art tri-leaflet valves included the additional limitations of claims 4 and 5 **was never rebutted**. To the contrary, Dr. Buller testified that the limitations of these claims were present in "essentially a three leaflet valve with stiffening means between the three leaflets." Tr. 531:24-532:11. Accordingly, as Dr. Loomis testified, prior art tri-leaflet valves attached to commissure points include the limitations of claims 4 and 5. Tr. 1088:4-1091:23.

Accordingly, no reasonable jury could find the asserted claims to be non-obvious.

IV. WILLFUL INFRINGEMENT

A. No Reasonable Jury Could Find by Clear and Convincing Evidence that Medtronic Acted Recklessly in the Face of an Objectively High Likelihood that It Infringed a Valid Claim of the '825 Patent.

A willfulness determination is not appropriate unless a patent holder proves by clear and convincing evidence that the accused infringer acted with objective recklessness, which is acting despite an objectively high likelihood that the actions infringe a valid patent, where the

objectively high risk was either known or should have been known to the accused infringer. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). "If the accused infringer's position is susceptible to a reasonable conclusion of no infringement, the first prong of *Seagate* cannot be met." *Uniloc USA, Inc. v. Microsoft Corp*., 632 F.3d 1292, 1310 (Fed. Cir. 2011).

The facts presented at trial demonstrate that there was no willfulness. Indeed, Edwards presented no willfulness case at all. While the Court submitted willful infringement to the jury over Medtronic's objection, the threshold question of whether a reasonable person would have considered there to be a high likelihood of infringement of a valid patent must be decided as a matter of law by this Court, subject to *de novo* review. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs.,* 682 F.3d 1003, 1006-07 (Fed. Cir. 2012). The jury's determination as to the objective prong of willfulness is therefore entitled to no deference.

Medtronic's defenses are strong, even if rejected by the jury. Under such circumstances, JMOL of no willfulness is appropriate. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1337 (Fed. Cir. 2009). In *DePuy Spine, Inc.,* the Federal Circuit affirmed JMOL of no willfulness even while finding that the plaintiff had presented evidence to support a finding of infringement. The "jury could have reasonably found for either party[.]" *Id.* Because the record, "viewed objectively," showed that the question of infringement was a "close one," the plaintiff "failed as a matter of law to satisfy *Seagate's* first prong." *Id.*

In other words, a plaintiff does not satisfy the first prong of the *Seagate* test merely by prevailing in its liability case. Instead, it must prove by clear and convincing evidence that there was an objectively high likelihood that the accused infringer would not prevail. In light of the non-infringement and invalidity evidence introduced at trial and in this Motion, no reasonable jury could find that Medtronic's defenses were frivolous or objectively without merit. At the

very least, insofar as there is any substantial evidence of willfulness under either prong (and there is not), Medtronic's infringement and invalidity defenses preclude a finding of willfulness.

A further basis for JMOL is Edwards' admissions in foreign proceedings (excluded before the jury) that irrefutably establishes that Medtronic's position was objectively reasonable. D.I. 145. In proceedings involving a European counterpart patent to the '825 patent, Edwards **admitted** the claim language of the European counterpart—which is virtually identical to that of the '825 patent—restricts the diameter of the **entire prosthetic valve assembly**, and not just the frame. D.I. 135, Ex. 2 at ¶ 42 ("specifying . . . **that the frame is compressible to an external diameter does not mean anything else than that in fact the entire prosthetic valve assembly is compressible** to said diameter").

Furthermore, in litigation in Germany, Edwards **admitted** that the CoreValve device cannot be delivered through an introducer that is less than 6.0 mm. D.I. 145, Ex. 1 at 15 ("The arguments in the briefs of **the parties agree** in the assumption that a catheter with an external diameter of 6 mm is necessary for the opposed prosthetic valve assembly.").

The Court excluded this evidence from the jury. Nonetheless, the Court should consider the German decision and Edwards' admissions in the EPO (submitted in D.I. 135 (Ex. 2 at 9); D.I. 145 (Ex. 1 at 15)) and determine that Edwards has not met its burden on the first prong of *Seagate*. In the alternative, a new trial should be granted to correct the exclusion of evidence about Edwards' admissions before the foreign tribunals.

B. No Reasonable Jury Could Find that Medtronic Knew or Should Have Known that There Was a High Risk of Infringement.

Even if the Court declines to grant judgment as a matter of law based on the first prong of *Seagate*, no reasonable jury could find that Edwards met its burden to show by clear and convincing evidence "that this objectively-defined risk (determined by the record developed in

the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *In re Seagate*, 497 F.3d at 1371.

Edwards presented no evidence—much less clear and convincing evidence—that it was unreasonable for Medtronic to believe that the self-expanding Nitinol frame of the CoreValve device, which in Medtronic's catheterization technique is delivered through a 6.0 mm introducer, did not meet the elements of any valid claim of the '825 patent.

During closing arguments, Edwards attempted to rebut Medtronic's assertion that it had no knowledge of the asserted claims until they issued in August 2011, by arguing that Dr. Cribier's disclosure was published in 1998. Tr. 1445:1-18. But Edwards own witness, Larry Wood, testified that Dr. Cribier's '481 patent (PTX 740), which is in the chain of priority for the '825 patent and issued in June 2005, was **not** asserted against Medtronic. Tr. 376:20-377:1. That fact confirms Medtronic's view that Dr. Cribier's invention is not applicable to the CoreValve device, and does not meet Edward's burden. Judgment as a matter of law is appropriate.

V. DAMAGES

A. There Is Insufficient Evidence to Support the Jury's Finding that Edwards Suffered $388 Million in Lost Profits.

1. No reasonable jury could award plaintiffs lost profits based on sales made by other companies.

Edwards pursued an impermissible "single-entity" theory, which ignored the corporate form of the plaintiffs.[7] That theory violates principles of corporate law, including respect for the corporate form. *Poly-America, L.P. v. GSE Lining Tech., Inc*., 383 F.3d 1303, 1311 (Fed. Cir. 2004) ("Poly-America and Poly-Flex may not enjoy the advantages of their separate corporate

[7] The '825 patent is owned by Edwards Lifesciences PVT, which exclusively licensed the patent to Edwards Lifesciences LLC. Tr. 353:14-24; 426:7-17. Their foreign sales affiliates are not plaintiffs in this case and do not own exclusive rights in the patents.

structure and, at the same time, avoid the consequential limitations of that structure—in this case, the inability of the patent holder to claim the lost profits of its non-exclusive licensee.")

Edwards' approach was already rejected by the Court. Tr. 1350. The Court determined that, at best, Edwards was only entitled to $285 million in lost profits. Tr. 1350:22-1351:15. The Court properly instructed the jury that:

> Only the profits lost by the named plaintiffs, Edwards Lifesciences LLC or Edwards Lifesciences PVT Inc., can be recovered. Edwards may not be compensated for lost profits of any of their affiliates or subsidiaries.

Jury Instruction 5.6. Given that clear direction, no reasonable jury could find that Edwards was entitled to $388 in lost profits.

The nature of Edwards' corporate structure precludes an award of lost profits for Edwards' affiliated companies that have no standing to sue. *Poly-America*, 383 F.3d at 1311. Lost profits are not available to a patent holder based on a related company's sales unless that company is an exclusive licensee (not the case here), or if profits of that subsidiary "flow inexorably" up to a named party, which Edwards failed to prove. *Mars, Inc. v. Coin Acceptors, Inc*, 527 F.3d 1359, 1367 (Fed. Cir. 2008); *Poly-America, L.P.*, 383 F.3d at 1311.

At trial, Edwards improperly presented a lost profits theory based on the average selling price of its SAPIEN and SAPIEN XT. Those sales are made by foreign affiliates that are not named plaintiffs. Edwards' damages expert was candid that his lost profits analysis improperly treated the entire Edwards conglomerate as "one company" and thus was not limited to profits of the Plaintiffs. Tr. 818:8-9 ("So the [$]393 [million] is certainly based on the profits of the entity as a whole."); Tr. 818:19-23 ("Mr. Woods said, from his point of view, it's – he thinks of it as all one company. That's the kind of information that I looked at and that makes economic sense, of course."). The evidence in the record does not support such a request because the mere fact that

related companies use consolidated financial statements is legally inadequate to support a claim for relief. *Mars, Inc.*, 527 F.3d at 1367; *Poly-America, L.P.*, 383 F.3d at 1311 (patent holder may not collect the lost profits of its affiliate because they are separate companies).

At a minimum, judgment as a matter of law must be entered that Edwards is only entitled to $285 million in lost profits, should the Court reject Medtronic's other arguments.

2. Lost profits cannot be based on a transfer price between affiliated companies.

Edwards is not entitled to even the remaining $285 million. Edwards relied on a transfer pricing agreement between the named plaintiffs and the un-named subsidiaries. This is insufficient to show lost profits to a named party.

This issue was squarely addressed in *Fujitsu Ltd. v. Tellabs, Inc.*, No. 09-4530, 2012 U.S. Dist. LEXIS 180860 (N.D. Ill. Dec. 21, 2012). There, the court was faced with facts closely aligned to those here: the named plaintiff was the parent of a non-exclusive licensee subsidiary; the subsidiary made the sales and paid a transfer price to the named plaintiff. *Id*. at *18-*21. The plaintiff, like Edwards, argued that the transfer price payments were the "profits" that the plaintiff made. *Id*. The court expressly rejected that argument, explaining that the transfer price paid by the subsidiary is regulated and calculated according to U.S. Tax Code requirements to avoid the consequences of 26 U.S.C. § 482. *Id*. at *24. The court noted that the word "profits" appears nowhere in the statute and held that the transfer price was "nothing more than [Plaintiff's] structuring its corporate relationships with its subsidiary . . . for [Plaintiff's] corporate benefit." *Id*. at *26. The court concluded that, "[Plaintiff's] tax strategy is designed to minimize the taxes [Plaintiff and subsidiary] pay to governmental entities in their respective countries and is not a transfer of profits from [subsidiary] to [Plaintiff]." *Id*.

The '825 patent is owned by Edwards Lifesciences PVT, which exclusively licensed the

patent to Edwards Lifesciences LLC. Both share a common parent (not a party to this case). DTX 143-0022. While Edwards seeks lost profits on the sales made by foreign distributors, it offered no evidence to show the flow of profits from the subsidiaries to either of the named plaintiffs. Edwards' damages expert performed no analysis to identify or ascertain the flow of profits between Edwards' entities. Tr. 812:5-813:1; 818:15-23; 820:9-823:13; 386:17-387:1. Non-named subsidiaries make a majority of the sales of the SAPIEN and SAPIEN XT outside the United States. Tr. 372:7-11; 372:24-373:11; 427:5-428:1; 428:8-10. Edwards Lifesciences LLC merely makes sales in the U.S.,[8] where the CoreValve has not been commercially sold.

As in the *Fujitsu* case, Edwards' damages expert opined that the plaintiffs are entitled to profits based on the transfer price paid by Edwards' foreign affiliates to the named plaintiffs. Tr. 818:4-14; Tr. 428:8-13; Tr. 429:3-16. But even for sales of products for which Edwards Lifesciences LLC did receive a transfer payment, Edwards has not established that the transfer price is a "profit" rather than a vehicle for minimization of taxes paid by the various Edwards' entities. Edwards' expert admitted the transfer pricing is a way to "satisfy taxation authorities in various countries." Tr. 801:10-13; *see also* Tr. 817:12-16; Tr. 819:19-24; Tr. 821:19-24. Without any showing that the transfer price is a transfer "profit" of Edwards Lifesciences LLC, rather than a tax strategy, Edwards has failed to meet its burden to show that Edwards Lifesciences LLC lost profits based on sales of SAPIEN and SAPIEN XT made by foreign subsidiaries.

Moreover, a percentage of the SAPIEN XT is manufactured in Singapore by Edwards Lifesciences AG. Tr. 386:17-387:1. Those units would not be subject to a transfer price at all. Edwards, however, did not provide any justification as to why it would be entitled to profits

[8] Edwards Lifesciences LLC allegedly makes a small amount of sales outside the United States, but offered no evidence showing the amount of those sales and thus failed to meet its burden.

based on foreign sales of SAPIEN XT manufactured and sold by a foreign subsidiary. Edwards' expert ignored the fact that since 2012, approximately 30% of SAPIEN XT's are manufactured in Singapore by one of Edwards' foreign subsidiaries. Tr. 386:17-387:1. Valves manufactured in Singapore and sold by a non-named subsidiary would not be subject to the transfer price, and accordingly, the named Plaintiffs would not be entitled to lost profits on the basis of such sales.

Edwards thus failed to meet its burden to show that it would be entitled to lost profits, and judgment as a matter of law is the proper remedy.

3. No reasonable jury could find that Edwards had the capacity to make the additional lost sales.

Edwards also failed to meet its burden of showing that it had the capacity to make the additional sales. It is undisputed that to be entitled to lost profits a party must show that it had the capacity to make the additional sales. *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1156 (6th Cir. 1978). No reasonable jury could find that Edwards met its burden to show that it would have been able to make all of Medtronic's sales. The only "evidence" that Edwards put forward showing that it had capacity to make the additional sales was conclusory statements made by Mr. Wood that Edwards would have had such capacity to increase proctoring, training and manufacturing. Tr. 396-399. Neither Mr. Wood nor Dr. Leonard, who relied exclusively on Mr. Wood for the capacity determination (Tr. 790:4-792:5), performed any analysis or pointed to any underlying facts to establish that Edwards could have made Medtronic's sales as of the date the patent issued. Edwards failed to show that it would have been able to make sales to hospitals where only the CoreValve is used. Rather, Dr. Leonard testified that he did **no analysis** as to whether certain hospitals were only trained on the CoreValve, such that on the day the patent issued, it would have been impossible for Edwards to make those sales because Edwards would first need to train the doctors how to use its devices. Tr. 838:22-841:2. Such conclusory and

unsubstantiated testimony is insufficient to meet Edwards' burden to show capacity to make the additional sales. *Gargoyles, Inc. v. United States.*, 113 F.3d 1572, 1577-78 (Fed. Cir. 1997).

4. No reasonable jury could find that Edwards is entitled to damages based on Medtronic's continued access sales.

As described in greater detail in Medtronic's motion for a new trial, continued access sales are exempt from infringement under the statutory safe harbor of 35 U.S.C. § 271(e)(1). *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1356-57 (Fed. Cir. 2012). In *Momenta*, the Federal Circuit made clear that the § 271(e)(1) safe harbor is expansive and encompasses any activity related to the "development and submission of information" to the FDA—including data for inclusion in post-approval records, which are simply required to be maintained for potential FDA inspection. *Id*. at 1357.

Data generated from Medtronic's continued access studies was actually used to satisfy clinical trial requirements that were necessary to obtain FDA approval. D.I. 156 at 3. Further, that data was used to both support FDA approval of the CoreValve and will be used to meet mandatory post-approval reporting requirements. *Id*. at 2-3, Ex. F. As such, the relationship between Medtronic's continued access sales and submission of information to the FDA is much less tenuous than that in *Momenta*. There is no question that Medtronic was required to, and did in fact, submit data related to its continued access study to the FDA. As such, Medtronic's continued access sales are exempt from patent infringement under the statutory safe harbor of 35 U.S.C. § 271(e)(1) and cannot be the basis for damages. Edwards' damages award includes $40.1 million based solely on products that were used in Medtronic's continued access study. D.I. 156. Because continued access sales are non-infringing, no reasonable jury could find that Edwards is entitled to the $40.1 million in damages based on Medtronic's continued access sales.

5. No reasonable jury could find that Edwards is entitled to lost profits based on shipment of treated porcine pericardial tissue.

As discussed above, no reasonable jury could find that Medtronic's shipment of treated porcine pericardial tissue from the United States to Mexico is an act of infringement under either § 271(f)(1) or (f)(2). As such, no reasonable jury could find that Edwards is entitled to lost profits based on those shipments. Edwards' expert testified that $107 million was based solely on the shipment of such tissue to Mexico. Tr. 844:19-845:2. Accordingly, even if the Court finds that Medtronic is entitled to lost profits based on the transfer price, Edwards is not entitled to the $107 million of those profits attributable to shipment of porcine pericardial tissue.

B. Edwards Is Limited to a Claim for a Reasonable Royalty.

As discussed above, no reasonable jury could find that Edwards is entitled to any lost profits. Accordingly, Edwards' recovery, if any, is limited to a reasonable royalty. Edwards' expert testified that Edwards would be entitled to a reasonable royalty of 5.7% on sales for which it is not entitled to lost profits. Tr. 772:15-23; 804:23-805:13. Thus, at most, Edwards is limited to a 5.7% reasonable royalty for any CoreValve sales found to be infringing.

C. An Accounting Is Necessary After Final Resolution of the Andersen Litigation to Avoid Double Recovery.

The damages award based on the jury's finding of infringement of the '825 patent overlap with those awarded based on the Andersen patent in the prior litigation, as fully set forth in Medtronic's Opening Brief in Support of Its Motion for a New Trial or Alternatively to Amend or Alter the Judgment. Edwards agrees that it cannot recover damages for the same sales in two different proceedings. D.I. 131 at 7. After final resolution of the Andersen litigation, any damages that were awarded must be deducted from any award based on an infringement finding regarding the '825 patent.

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